MAR - 8 2001

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K003861**

Applicant information:

Date Prepared:	February 22, 2001
Name:	**Benz Research and Development**
Address	P.O. Box 1839 Sarasota, FL 34230-1839
Contact Person:	Jose Ors, Ph.D.
Phone number:	(941) 758 8256
USA Consultant:	Med-Vice Consulting, Inc. Martin Dalsing, President 623 Glacier Drive Grand Junction, CO 81503
Phone number	(970) 243-5490
Fax number	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lens for Daily Wear (lathe-cut)**

Purpose of 510(k):

The purpose of this 510(k) submission is to obtain FDA approval for Benz Research and Development to market and sell a visibility handling tint version of the already approved clear version of methafilcon A contact lenses. Incorporation of a color additive for the first time into an all ready approved clear version of contact lens material requires a 510(k) submission.

Equivalent Devices:

The **BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lens for Daily Wear** is substantially equivalent to the **BENZ –MF (clear) (methafilcon A) Soft Contact Lens for Daily Wear,** with the exception of the addition of a color additive.

Device Description:

The **BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lenses for Daily Wear** are fabricated from methafilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 55% water by weight. The lenses are available in clear and with a blue visibility handling tint, phthalocyaninato(-2) copper. The ionic material is a co-polymer of 2-hydroxyethylmethacrylate (2-HEMA), methacrylic acid crosslinked with ethylene glycole dimethacrylate, plus an initiator and phthalocyaninato(-2) copper color additive to accomplish the intended color effect.

The physical properties of the lens are:

Refractive Index	1.515 (dry) 1.404 (hydrated)
Color Pigment Name	Phthalocyanine Blue
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	55 % ± 2%
Specific Gravity	1.099 (hydrated)
Oxygen Permeability	18.2×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (Revised Fatt Method).

Intended Use:

The BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism.

The spherical lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. Persons who exhibit refractive astigmatism not exceeding 10 diopters may wear the toric lens.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Preclinical Testing Results:

The Manufacturing/Chemistry test results of the **BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lenses for Daily Wear** are identical to the Benz Research and Development clear version of contact lenses manufactured from the methafilcon A material (predicate device), with exception of the addition of the color additive (Phthalocyanine Blue).

The materials used in the **BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lenses for Daily Wear** have proven biocompatibility.

Substantial Equivalence:

The following matrix illustrates the production method, lens function and material characteristics of the **BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lens for Daily Wear,** as well as the predicate device.

	Characteristic	BENZ -MF (Visibility Tint)	BENZ -MF (Clear) (predicate device)
1.)	Production Method	Lath-cut	Lath-cut
2.)	Lens Function	Refractive medium that focuses light rays from near and distant objects on the retina while compensating for refractive error, including astigmatism.	Refractive medium that focuses light rays from near and distant objects on the retina while compensating for refractive error, including astigmatism.
3.)	Material	hydrophilic polymer	hydrophilic polymer
4.)	Water Content	55%	55%
5.)	Polymer Content	45%	45%
6.)	Polymer	methafilcon A	methafilcon A
7.)	Visibility Handling Tint	Blue	Not applicable
8.)	Color additive	phthalocyaninato(-2) copper	Not applicable
9.)	Light Transmittance	> 95%	> 95%
10.)	Toxicology Analysis	Within normal limits	Within normal limits

Substantial Equivalence Matrix

SUMMARY:

Based on the intended use, product, performance and biocompatibility information provided in this notification, the **BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lenses for Daily Wear** have been shown to be substantially equivalent to the **BENZ (clear) (methafilcon A) Soft Daily Wear Contact Lenses for Daily Wear.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

BENZ RESEARCH & DEVELOPMENT, Inc.
c/o Mr. Martin Dalsing
President, Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K003861
Trade Name: BENZ-MF (visibility handling tint) (methafilcon A) Soft Contact Lens for Daily Wear (blue visibility tint, lathe-cut)
Regulatory Class: II
Product Code: 86 LPL
Dated: December 8, 2000
Received: December 13, 2000

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **BENZ –MF (visibility handling tint) (methafilcon A) Soft Contact Lens for Daily Wear (lathe-cut)**

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(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003861

Prescription Use X or Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)